AUG 1 0 2001

510(k) Notification
Polygraf ID with Polygram 98 software

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 SKOVLUNDE
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Contact person for this submission: Tove Kjaer
Date submission was prepared: May 10, 2001

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Polygraf ID with Polygram 98 software

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Polygraf ID	78 FFX	II	21 CFR 876.1725
Polygram 98 Esophageal Manometry Testing Application	78 FFX	II	21 CFR 876.1725
Polygram 98 Anorectal Function Testing Application	78 FFX	II	21 CFR 876.1725

3. Predicate Device Identification:

The scientific technology and the functionality and intended use of the Polygraf ID with Polygram 98 software are equivalent to Medtronic Functional Diagnostics A/S ' Anorectal Manomentry Analysis Module (K972439), Polygraf HR (K872712, Polygram SW basemodule (K946322), Esophageal Manometry Analysis Module

(K961070), Esophageal Manometry System (EM System) (K992713) and Polygraf 98 Anorectal Function Testing Application (K000386).

4. Device Description:

The Polygram 98 software is used together with Polygraf ID to assess the function of the entire gastrointestinal tract and the pelvic floor. Data is collected along the entire gastrointestinal tract by means of catheter/sensors and a recording device (PolygrafID) and then analyzed. The results are used to help diagnose motility disorders.

The parameters are presented during the capture and are also recorded for later display, analysis and reporting.

In its daily use, a trained tecnician and/or a physician are the main user of the system.

The main tasks when performing a manometry procedure with a stationary manometry system are:

- Prepare equipment including calibration
- Enter patient/study demographic information
- Perform procedure and obtain relevant data
- Review, analysis and post procedure activities
- Create and print a report

The Polygram 98 software runs on Microsoft Windows® 98.

5. Intended Use:

The Polygraf ID in conjunction with the Polygram 98 software is intended to record, store, view and analyze pressure, pH, EMG, swallow and respiratory data on-line anywhere in the gastrointestinal tract (pharynx, esophagus, stomach, duodenum, Sphincter of Oddi, small bowel, colon and anorectal area including rectum and pelvic floor) to assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders.

Designated catheters are required for measurement in each specific area.

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6. Table of Device Similarities and differences to predicate device

Manufacturer	Medtronic Synectics AB	Medtronic Functional Diagnostics A/S	Medtronic Functional Diagnostics A/S	Comments
510(k) number for EM System	***Predicate devices*** • Polygraf HR – **K 872712** • Polygram software, base module – **K 946322** • Esophageal Manometry Analysis Module – **K 961070**	***Predicate devices*** Esophageal Manometry System, (EM System)i.e - Polygraf ID & - Polygram '98, Esophageal Manometry Application - **K 992713**	***Modified Device*** GI Motility System i.e. - Polygraf ID & - Polygram 98, Esophageal Manometry Application & - Polygram 98 Anorectal Function Testing Application K number to be decided	The GI Motility System i.e. Polygraf ID in conjunction with Polygram 98 EM and AFT Applications is used to assess the function of the GI tract i.e. pharunx, esophagus and its associated organs (lower and upper esophageal sphincters), the stomach, duodenum, sphincter of oddi, small bowel, colon, rectum, anal canal and pelvic floor. Data is collected along the entire gastrointestinal tract by means of a catheter and recording device and then analyzed. The results are used to help diagnose motility disorders.
510(k) number for AFT system	***Predicate Device*** • Anorectal Manometry Analysis Module for Polygraf HR – **K 972439**	***Modified Device*** • Polygram 98 Anorectal Function Testing Application - **K 000386**	Consolidated in the above	

General:	***Predicate devics:*** - all	***Predicate devics*** - all	***Modified Device*** - GI Motility System	***Explanation of the differences compared to the Predicate devices***
Intended Use / Indication of Use for EM	Record, store, view and analyze data on line in the gastrointestinal tract to assist in the diagnoses of gastrointestinal disorders.	Record, store, view and analyze data on line in the gastrointestinal tract to assist in the diagnoses of gastrointestinal disorders.	The Polygraf ID in conjunction with the Polygram 98 is intended to record, store, view and analyze pressure, pH, EMG, swallow and respiratory data on-line anywhere in the gastrointestinal tract (pharynx, esophagus, stomach, duodenum, Sphincter of Oddi, small bowel, colon and anorectal area including rectum and pelvic floor) to assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders. Designated catheters are required for measurement in each specific area.	One consolidated indication for use that covers the entire GastroIntestinal tract.

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Intended Use / Indication of Use for AFT	Analyze pressure data recorded from the lower gastrointestinal tract.	Analyze pressure data recorded from the lower gastrointestinal tract.	Consolidated in the above	--
Intended Populations	Infant, Pediatric to Adults	Infant, Pediatric to Adults	Same	--
Sterilization	Accessories are not supplied sterile, manufacturer label the accessories with cleaning instructions.	Accessories are not supplied sterile, manufacturer label the accessories with cleaning instructions.	Same	--
Biocom-patibility	The Sensors are the only parts that come into contact with the patients.	The Sensors are the only parts that come into contact with the patients.	Same	--

Technical Features:	***Predicate devices*** - Polygraf HR	***Predicate Device*** - Polygraf ID	***Modified Device*** - Polygraf ID	***Explanation of the differences compared to the predicate devices***
Number of Channels	Up to 16	4-16 channels	4-16 channels	Enhanced performance
Sampling rate	1/128 to 128 Hz	105-1674 Hz	105-1674 Hz	Enhanced performance
Power supply	9 –12 V DC	24 V DC	24 V DC	110-230 V Power Supply in one
Measuring range	0-9 pH	-2.5 Vpm, 5 % to 2.5 Vpm 5%	-2.5 Vpm, 5 % to 2.5 Vpm 5%	Enhanced performance
Insulation	Burr Brown722 dual isolated DC/DC converter	HCPL-0710. NMV 2405S, and safety power supply: class I	HCPL-0710. NMV 2405S, and safety power supply: class I	Enhanced performance, isolation provided also within each module of 4 channels (4, 8, 12, 16.)
Current consumption	260 mA nom standard (8bit)	Max 0.8 A	Max 0.8 A	Enhanced performance requires more power
Communication	Optical serial RS 232	USB (Universal Serial Bus)	USB (Universal Serial Bus)	Enhanced performance (band width)
Resolution	8 bit	22 bit	22 bit	Enhanced performance
Dimension	11.2" x 2" x 6 "	14" x 8.8" x 2.8"	14" x 8.8" x 2.8"	More channels require more space
Weight	1 050 gz	< 3 000 g	< 3 000 g	Larger box weight more
On-line monitoring	Via PC Screen	Via PC Screen	Same	---

Features:	***Predicate devices***	***Predicate Device***	***Modified Device***	***Explanation of the differences compared to the Predicate devices***
	- Base module & - EM Analysis Module, - Anorectal Manometry Analysis Module for Polygraf HR	- Polygram 98, Esophageal Manometry Application - Polygram 98 Anorectal Function Testing Application	- Polygram 98, EM and AFT Applications	

Data displayed	Raw signal data	Raw signal data	Same	
User commands	Menu selections	Menu selections	Same	

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Signals to analyze in EM	Ph, pressure, flow, volume, respiration, oxygen saturation, pulse rate, body position, snoring	Pressure, respiration and swallow	Pressure, pH, EMG, respiration and swallow	This is what has been implemented in this version.
Signal to measure in AFT	Pressure, EMG	Pressure, EMG	Consolidated in the above	
User commands	Menu selections, keyboard combinations, screen "buttons"	Menu selections, keyboard combinations, screen "buttons"	Same	--
Analyzing signals	Overall, pressure, pH, Respiration, Swallow and EMG is used to access the function of the GI tract **LES and UES/pharynx evaluations**: Location/anatomy, Rest and relaxation pressures, coordination. **Esophageal evaluations**: Contractions, coordination and peristalsis. **Anorectal evaluations**: Location/anatomy, Rest, squeeze, strain, cough, and relaxation pressures, coordination, sensation.	Pressure, pH, Respiration, Swallow and EMG is used to access the function of the GI tract **LES and UES/pharynx evaluations**: Location/anatomy, Rest and relaxation pressures, coordination. **Esophageal evaluations**: Contractions and peristalsis. **Anorectal evaluations** : Location/anatomy, Rest, squeeze, strain, cough, and relaxation pressures, coordination, sensation.	Same. **For stomach, duodenal, sphincter of oddi, small bowel and colon evaluations**: Contractions, coordination and peristalsis (similar to the esophageal and/or anorectal area)	A generic analysis tool (already in the program) can be used to access the function of the stomach, duodenal, sphincter of oddi, small bowel and colon by e.g. calculating maximum, minimum and mean pressures measured in the different areas of the GI tract
Calculated parameters	Maximum, minimum, mean and median pressures, duration, coordination/time/velocity, location/length	Maximum, minimum, mean and median pressures, duration, coordination/time/velocity, location/length	Same	--
Reports	Signal tracings and reports. Optionally selections only.	Signal tracings and reports. Optionally selections only.	Same	--
Patient database	Relational database with logical patient-recording relations	Relational database with logical patient- recording relations	Same	--
Additional data	User definable additional patient/recording parameters	User definable additional patient/recording parameters	Same	--
User help system	Online help system with descriptions of procedures	Online help system with descriptions of procedures	Same	--
Signal review method	Time – tracing based	Time – tracing based	Same	--
Recording control	Real time monitoring of signals	Real time monitoring of signals	Same	--

Calibration	Adjustable and fixed gain method. Monitoring of calibration result for range and resolution requirement.	Adjustable and fixed gain method. Monitoring of calibration result for range and resolution requirement.	Same	–
Recording configuration	A template is used for each type of recording. User definable.	A template is used for each type of recording. User definable. ('templates' are now called 'protocols')	Same ('templates' are now called 'protocols')	–
Programming language	'C'	C++, Visual Basic	C++, Visual Basic	
Operating system	Windows 3.11, 95	Windows 98	Windows 98	Enhanced performance

7. Assessment of non-clinical performance data for equivalence:

Verifications results show that the enhanced system performs as its predicate system.

8. Assessment of clinical performance data for equivalence:

Clinical trials have not been performed. This system does not raise any new safety or performance issues.

9. Biocompatability:

Not applicable

10. Sterilization:

Not applicable

11. Standards and Guidances:

The Polygraf ID conforms to the following voluntary and mandatory standards:

- EN 60601-1, Medical equipment
- EN 60601-1-1, Electrical Safety
- EN 60601-1-2, Electro magnetic Compatibility
- CAN/CSA 22.2 No. 601.1 – M90

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Ms. Tove Kjaer
Regulatory Affairs Specialist
Medtronic Functional Diagnostics
Tonsbakken 16 - 18
DK-2740 Skovlunde
DENMARK

Re: K011472
Polygraf ID with Polygram '98 Software
(Modified Software)
Dated: May 10, 2001
Received: May 14, 2001
Regulatory Class: II
21 CFR §876.1725/Procode: 78 FFX

Dear Ms. Kjaer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indication for Use Statement

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510(k) Number (if known): K011472

Device Name: **Polygraf ID with Polygram 98 software**

Indications for Use:

The Polygraf ID in conjunction with the Polygram 98 software is intended to record, store, view and analyze pressure, pH, EMG, swallow and respiratory data on-line anywhere in the gastrointestinal tract (pharynx, esophagus, stomach, duodenum, Sphincter of Oddi, small bowel, colon and anorectal area including rectum and pelvic floor) to assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders.

Designated catheters are required for measurement in each specific area.

MRI Compatibility Statement:

The Polygraf ID with Polygram 98 Software is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011472

(Optional Format 1-2-96)